

### REMARKS

Reconsideration and withdrawal of the rejections set forth in the Final Office Action dated October 1, 2004 are respectfully requested. Applicants petition for a one-month extension of time in which to file the response. A separate petition for the extension accompanies this paper.

#### I. Amendments

Claims 1 and 30 are amended to omit the option of L being -CH<sub>2</sub>-.

A typographical error in the specification is corrected.

#### II. Rejections under 35 U.S.C. §103

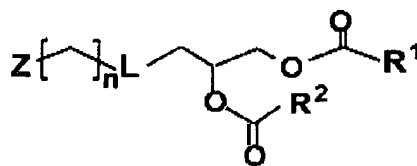
Claims 1-15 and 30-33 are rejected under 35 U.S.C. § 103(a) as allegedly upatentable over Wolff *et al.* (U.S. Patent No. 5,965,434).

Claims 15 and 16 are rejected under 35 U.S.C. § 103(a) as allegedly upatentable over Wolff *et al.* further in view of Allen *et al.* (U.S. Patent No. 6,056,973).

Claims 17 and 18 are rejected under 35 U.S.C. § 103(a) as allegedly upatentable over Wolff *et al.* further in view of Zalipsky *et al.* (U.S. Patent No. 5,395,619).

#### A. The Invention

The present invention relates to a liposome composition, and to a method of delivering an agent with the liposomes, comprising a lipid having the formula:



wherein each of  $\text{R}^1$  and  $\text{R}^2$  is an alkyl or alkenyl chain having between about 8 to about 24 carbon atoms;  $n = 0-20$ ; consisting of (i)  $-\text{X}-(\text{C}=\text{O})-\text{Y}-$ , (ii)  $-\text{X}-(\text{C}=\text{O})-$ , wherein  $\text{X}$  and  $\text{Y}$  are independently selected from oxygen,  $\text{NH}$ , and a direct bond, and (iii)  $-\text{O}-\text{CH}_2-$ , and  $\text{Z}$  is a weakly basic moiety that has a  $\text{pK}$  of less than about 7.4 and greater than about 4.0.

### B. The Prior Art

WOLFF ET AL. teach lipids of the general form A-B-C (Col. 5, line 5) where A is a hydrophobic moiety (e.g. a lipid), B is a spacer, and C is a cationic, pH-sensitive moiety.

ALLEN ET AL. teach a conjugate of the form "targeting ligand-polymer-lipid".

ZALIPSKY ET AL. describe a lipid-polymer conjugate where a lipid is attached to a hydrophilic polymer.

### C. Analysis

The Examiner has maintained the rejection, noting that when L of the present invention is CH<sub>2</sub>, the resulting compound is homologous to a compound disclosed by Wolff *et al.*

As noted above, claims 1 and 30 are amended to omit the embodiment where L is CH<sub>2</sub>. With this amendment, the compounds claimed are not disclosed by Wolff *et al.*, as outlined in Applicants' reponse submitted June 8, 2004. Since all of the claim limitations are not shown or suggested by Wolff *et al.*, the present claims are not obvious in view of Wolff *et al.* alone.

With respect to the rejection of claims 15 and 16, rejected over a combination of Wolff *et al.* in view of Allen *et al.*, and claims 17 and 18, rejected over a combination of Wolff *et al.* in view of Zalipsky *et al.*, these are patentable over the cited art because if an independent claim is nonobvious under 35 U.S.C. then any claim depending therefrom is nonobvious. (M.P.E.P. § 2143.03). Claims 15-18 are dependent, directly or indirectly, on claim 1, which defines over the cited primary reference to Wolff *et al.* for the reason given above. The secondary references, Allen *et al.* and Zalipsky *et al.* cited for teachings of ligands and polymer chains, do not disclose the missing information from Wolff *et al.* to show all of the present claim limitations. Accordingly, withdrawal of the rejections under 35 U.S.C. § 103 is respectfully requested.

**III. Conclusion**

In view of the foregoing, the applicant submits that the claims pending patentably define over the cited art. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4402.

Respectfully submitted,

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Judy M. Mohr  
Judy M. Mohr  
Registration No. 38,563

**Correspondence Address:**

Customer Number 27777  
ALZA Corporation  
C/o Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933